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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/535,585

08/10/2005

Hisae Kume

SPO-121

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EXAMINER

SINGH, SATYENDRA K

ART UNIT

PAPER NUMBER

1657

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11/19/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/535,585	<b>Applicant(s)</b> KUME ET AL.	
	<b>Examiner</b> SATYENDRA K. SINGH	<b>Art Unit</b> 1657	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 August 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 and 31-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 and 31-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 August 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission (along with Hisae Kume's affidavit filed under 37 CFR 1.132) filed on August 19<sup>th</sup> 2008 has been entered.

Claims 25-30 have been canceled by applicant's current amendments to the pending claims.

Claims 1-24 (as currently amended) and newly added claims 31-33 are examined on their merits, herein, for the applicant's **elected specie** for milk protein hydrolysate, "**whey protein isolate** (WPI)".

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-24 and 31-33 (as currently amended) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 (as currently amended) recites the limitation of "a high oleic acid-containing oil and milk lecithin and/or soybean lecithin as lipids", which is ambiguous and confusing. It is unclear as to what exactly is encompassed by said recitation as presented in the claim. The relative term "**high** oleic acid-containing oil" fails to

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provide a clear boundary (metes and bounds) as to how high the content of oleic acid in the oil has to be in order for it to be considered "high oleic acid-containing oil" as currently required by the claimed limitation. Since, the disclosure fails to provide an explicit definition for said limitation, an artisan of ordinary skill would not know how to meet such limitation, and therefore, the recitation is deemed to render claimed invention indefinite. Appropriate correction is required.

2. Claims 3 and 19 recite the limitation "**the** whey" in line 1 of the respective claims. There is insufficient antecedent basis for this limitation in the broader claim 1 or claim 17, respectively. Appropriate correction is required.

3. Claim 31 recites the limitation "**the** inflammatory cytokine" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the broader claim 17. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names **joint inventors**. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1-24 and 31-33 (as currently amended) are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Gray et al (US 5,714,472, [A]) in view of Kawai et al (1989; [U2]), Davis et al (US 6,998,259 B1, [B]), and Siegenthaler (1983; [U]), taken with Fritsche et al (US 6,737,076 B2; [C]) and et al (US 4,499,076; [A2]).

Claims (as currently amended) are generally directed to **a nutritional composition** (suitable for liver disease patients, and/or patients under high level of invasive stress; see instant claim 17) comprising a milk protein hydrolysate (applicant's elected specie, **whey protein isolate**, WPI, that **may be** obtained by enzymatic hydrolysis using an endoprotease from *Bacillus licheniformis*, and trypsin, and ultrafiltration, resulting in an HPLC separation profile as shown in figure 1 of the instant specification) in an amount of 0.9 to 3 g per 100 mL of the composition and a protein derived from fermented milk in an amount of 2.5 to 4.5 g per 100 mL of the composition, as proteins; a **high** oleic acid-containing oil and milk lecithin and/or soy lecithin, as lipids; and palatinose (i.e. isomaltulose) in an amount of 4-15 g per 100 ml of the composition as a carbohydrate; and **a method of providing nutrition to a patient** having liver disease and/or a high level of invasive stress (such as liver cirrhosis or hepatic failure) comprising administering said nutritional composition to such a patient. (see instant claims 1, 9, and 17, as currently amended, and newly added claims 31-33, in particular)

*"[E]ven though **product-by-process** claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).*

Gray et al [A] teach an enteral formulation (and a method for providing nutrition using a composition comprising protein, high fat and low carbohydrate; designed for optimized nutrient absorption and wound healing; i.e. for patients under high level of invasive stress) comprising an improved protein source (such as whey protein hydrolysate; see Gray et al, abstract, summary of the invention, column 4; column 5, lines 43-48; examples 2-3, and claims, in particular); a high oleic acid-containing lipid source (as exemplified in the instant specification on page 14, lines 1-3; such as soy oil; see Gray et al, columns 5-6, in particular) including soy oil and lecithin (see

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Gray et al, column 5, lines 35-37; examples 1-2, in particular); and carbohydrates (such as maltodextrin and corn starch. It is to be noted that Gray et al recognize the need for optimization of an enteral nutritional composition (suitable for patients under high stress) in order to reduce the risk of over hydration, hyperglycemia, and carbohydrate intolerance, and hence the emphasis on appropriate protein content (a reasonable amount such as about 9 g/100 ml of the formulation; see Gray et al, column 7, formula example No. 3, in particular) and high lipid diet (see Gray et al, summary of the invention, column 2, lines 43-55, in particular).

However, a nutritional composition comprising a protein derived from **fermented milk** (as recited in instant claims 3-5 and 11-13); wherein the **palatinose** is used as a carbohydrate; and wherein the milk protein hydrolysate may be obtained by an enzymatic (using an endoprotease from *B. licheniformis*, alcalase and trypsin) hydrolysis of a **whey protein isolate (WPI)**; see instant claims 6-8 and 14-16), is not explicitly disclosed by the referenced invention of Gray et al.

Siegenthaler [U] discloses the potential nutritive value of cultured dairy products (i.e. fermented milk products such as **fresh cheese, quark**, and yogurt; see Siegenthaler, summary, page 252-254, in particular) that are especially suitable for use in children (akin to patients with suboptimal digestive system; in place of fluid reconstituted milk preparations that are linked with lactose-intolerance, or handling-related diarrhea among many populations) as it provides many benefits including longer shelf-life of the product at ambient temperatures as well as aid in the digestion of residual lactose after ingestion of such fermented milk compositions.

Davis et al [B] teach a milk protein hydrolysate which is obtained by the enzymatic hydrolysis of **WPI** (whey protein isolate such as BiPRO<sup>TM</sup>; see Davis et al, abstract, summary of the invention, columns 3, 5, 9-10, and claims, in particular) which can be used as a source of antihypertensive peptides (such as having **ACE-inhibitory activity**) derived from whey proteins

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(i.e. suitable and beneficial for use in nutritional compositions for patients under high level of invasive stress).

In addition, Kawai et al provide a disclosure for the benefits of **palatinose** (or isomaltulose as a source for low-caloric carbohydrate) for patients with conditions such as diabetes, and explicitly suggest its use in a variety of nutritional supplements as a non-calorigenic sweetener (see Kawai et al, page 338, Introduction, in particular) that causes no known side effects, even at high dose levels (such as 50 g/150 ml administered orally to human NIDDM diabetic patients) in said patient populations.

Therefore, given the detailed disclosure for all the components of a nutritional composition (and its suitability and use in providing nutrition to patients under high level of stress and trauma) used in the cited prior art references, it would have been obvious to a person of ordinary skill in the nutritional art, at the time this invention was made, to modify (i.e. combination and/or substitution of known components) the composition of Gray et al such that it includes a protein from fermented milk such as from fresh cheese, quark (as taught by Siegenthaler); a milk protein hydrolysate which is obtained by enzymatic hydrolysis of a WPI (as explicitly taught by the referenced invention of Davis et al); and a non-calorigenic carbohydrate such as palatinose as a sweetener (as explicitly suggested by Kawai et al).

One of ordinary skill in the art would have been motivated to modify the composition of Gray et al with a reasonable expectation of success using the combined teachings and suggestions of Siegenthaler, Kawai et al, and Davis et al because they explicitly provide suggestions (such as ease of digestibility, anti-hypertensive properties of peptides derived from WPI, and non-calorigenic substitute for use as a carbohydrate source) and method of preparation

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of such composition (see discussion above) that are suitable for use with patients having compromised digestive system, and/or under high invasive stress conditions, as intended by instant invention.

The claimed limitation of specific ranges of protein contents (as recited for milk protein hydrolysate and for protein derived from fermented milk; see instant claims 1, 9 and 17, as currently amended) would have been obvious to an artisan of ordinary skill in the nutritional formulation art, as evidenced by the fact that Gray et al disclose and exemplify a similar protein amounts of about 9 g per 100 ml in their ready-to-use enteral product formulation (see also discussion above). Moreover, **low-protein dietary formulations** have been suggested in past to be used for patients with chronic liver diseases as one of the basic therapeutic tools as disclosed explicitly by et al (see suitability for use in various liver diseases such as liver cirrhosis, or hepatic failure, etc.; Ohasi et al, column 1, 2<sup>nd</sup> paragraph, and column 4, 2<sup>nd</sup> paragraph, in particular) in order to avoid side effects such as diarrhea, or even renal insufficiency, etc., and therefore, such optimization in the amounts of proteins (i.e. from various protein sources) used in the nutritional formulations would have been routine for an artisan of ordinary skill in the art at the time this invention was made. Similarly, the limitation of the specific amount of palatinose (useful as a caloric sweetener) used in the nutritional composition would have been obvious to a person of ordinary skill in the clinical art as Kawai et al disclose the use of a relatively higher level of oral palatinose administration without significant side effects in patients populations in need thereof. The limitations of newly added claim 31 “wherein the increase of the inflammatory cytokine is suppressed in the patient administered with the nutritional composition” is taken to be an intrinsic property of the nutritional composition comprising whey



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protein hydrolysate, as taught by the combined teachings of the cited prior art references of record, especially since the use of such formulations have been shown to be suitable for patients with various types of liver diseases and disorders, as discussed above.

Similarly, the claimed limitations of instant claims 7-8 and 15-16 (which is a permeate obtained by further treatment with an ultrafiltration membrane having a molecular weight of 10,000 Daltons, and wherein the chromatogram from reversed phase HPLC separation is shown in Fig. 1.) would have been a matter of routine optimization to a person of ordinary skill in the art at the time this invention was made, as evidenced by the disclosure of Davis et al (and as supported further by the invention of Fritsche et al [C] that discloses the use of alcalase (i.e. an endoprotease from *B. licheniformis*), trypsin, and other endoproteases, or combinations thereof, to hydrolyze protein sources such as WPI; see column 4, lines 44-65; columns 5-6; example 2-3; and use of ultrafiltration and HPLC separation procedures to obtain the peptides derived from the hydrolysate of WPI) for the preparation of enzymatic hydrolysate of WPI and its use as a component having significant nutritional as well as health benefits.

Thus, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill in the nutritional art at the time the claimed invention was made.

*As per MPEP 2111.01, during examination, the claims must be interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, F.3d, 2004 WL 1067528 (Fed. Cir. May 13, 2004)(The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation.). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).*

***Response to Applicant's 103(a) Rejection Arguments***

Applicant's arguments (along with Hisae Kume's affidavit/declaration under 37 CFR 1.132) filed on August 19<sup>th</sup> 2008 (as they pertain to the prior art rejection of record) have been fully considered but they are not persuasive for the following reasons of record.

Applicants seem to be arguing about the presence of "whole proteins" in the claimed composition (see remarks, page 7, 4<sup>th</sup> and last paragraphs, in particular; and page 8, 2<sup>nd</sup> paragraph, in particular) of the instant application. However, it is noted that the composition as claimed, while comprising a "milk protein hydrolysate" and "protein derived from fermented milk", does not require the presence of "whole proteins" as currently argued by applicants. The declaration and evidentiary data in the form of chromatographic analyses of milk, before and after fermentation, provided by Kume is fully appreciated and considered. However, the protein component of the claimed nutritional composition, as recited, is not limited to the presence of "whole proteins" (see instant claims 1, 9 and 17, in particular). The limitation of "protein *derived from* fermented milk" can be interpreted to include any protein or fragment thereof (theoretically or practically derived from fermented milk), and therefore is not limited to a substantial presence of "whole proteins", as currently discussed and argued by applicants.

Applicant's arguments regarding the cited prior art reference of Ohashi et al (see remarks, pages 9-10) is not found to be persuasive because Ohashi et al clearly disclose the use of such nutritional composition comprising carbohydrates, fats, amino acids, vitamins and minerals, etc. for patients that have various types of liver diseases such as liver cirrhosis, hepatic insufficiency, etc. (see column 4, 2<sup>nd</sup> paragraph, in particular). Moreover, the claimed invention of record (see instant claim 17, a "method for providing nutrition to a patient having liver disease....as a

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carbohydrate) does not specifically require the limitations such as a patient population having “increased metabolic activity...support wound repair” as pointed out and argued by applicants (see page 9, last paragraph, in particular). therefore, the teachings of Ohashi et al when taken in combination with the disclosure of Gray et al, as relied upon in the rejection of record, are not “opposite to the purpose of the enteral formulation of Gray et al”, as currently argued by applicants.

Applicant’s argue that *"The Fermented milk of Siegenthaler contains significant amounts of whole proteins; therefore, one skilled in art would not have been motivated to combine the teachings of Siegenthaler with that of Gray et al. Thus, the applicants respectfully submit that one of ordinary skill in the art would have had no reason to combine fermented milk products into the enteral formulation of Gray et al"*, which is not found to be persuasive because such combination (i.e. increasing the protein content of the nutritional supplement) would be obvious to an artisan of ordinary skill in the clinical nutrition art, especially for patients that may demonstrate higher metabolic activity, and thus require higher amounts of certain components, such as nitrogen source in the form of proteins, in the nutritional composition to be administered enterally.

The argument that purpose of Davis et al is different and it does not suggest the use of hydrolyzed whey proteins to patients under high levels of invasive stress (see remarks, page 10, last paragraph, in particular), is duly noted. However, Davis et al explicitly disclose the health benefits such as antihypertensive properties (i.e. ACE-inhibitory activity) of peptides derived from whey protein hydrolysates that can be supplemented by an artisan of ordinary skill into a

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nutritional composition in order to provide better and effective nutrition to patients with liver disease or for that matter patients under high levels of invasive stress.

Applicant's argument regarding the use of palatinose for modifying the composition of Gray et al in view of the disclosure provided by Kawai et al (see remarks, page 11, in particular), as being unsuitable, is not found to be persuasive because Kawai et al provide the motivation to use a sugar substitute in the form of palatinose for patients that need a low glycemic index carbohydrate as a sweetener, and demonstrate the fact that a relatively higher amounts such as 50 g per 150 ml dose of palatinose did not show any significant side effects in diabetic patients when administered orally. Thus, in the absence of any evidence to the contrary, an artisan of ordinary skill in the clinical nutrition art would have been motivated to use palatinose in the nutritional composition of Gray et al in order to supplement a low caloric sweetener for patients in need thereof.

The invention as a whole, therefore, fails to distinguish itself over the combined teachings of the cited prior art references of record, and thus, the rejection of record is properly made and maintained.

### ***Obviousness-type Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided

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the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-24 and 31-33 (as currently amended) are/remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 37 and 38 of copending Application No. 10/487,237 (from the same inventive entity and same assignee, Meiji Dairies Corp. Tokyo, JP). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 2, 37 and 38 in the copending application 10/487,237 are also directed to a composition (and methods of using the said composition) comprising protein (such as milk proteins), a lipid (such as high oleic acid containing oils, and milk phospholipids), and a carbohydrate (such as palatinose and/or trehalulose). Although, the composition as recited in the copending application 10/487,237 requires certain range of energy percentage supplied from the components (such as proteins, lipids, and carbohydrate), such distribution of the components based on the caloric input would have been a matter of routine optimization to a person of ordinary skill when using the said composition for a particular patient or subject population depending on the nutritional/caloric requirements. The two sets of composition claims are largely coextensive, and thus raise an issue of obviousness-type double patenting.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Response to Applicant's ODP Arguments***

Since, applicants have deferred a substantial response against the ODP rejection of record (see remarks, page 12, 3<sup>rd</sup> paragraph, in particular) until an allowable subject matter is established in the instant application, the rejection of record as set forth above is still deemed proper, and is therefore, properly maintained.

### ***Pertinent prior art not relied upon in the Rejections***

The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

1. FUCHS et al. (US 6,592,863 B2; issued on July 15, 2003), Method to provide nutritional composition; abstract, summary, examples and claims.
2. BUCKE et al. (US 4,587,119; issued on May 6, 1986), Method of reducing dental plaque formation with products for human or animal consumption using isomaltulose sucrose substitute; abstract, columns 5-6.
3. OJIMA et al. (US 7,029,717 B1; issued on April 18, 2006), Sucralose-containing composition and edible products containing the composition, abstract, columns 7-8, in particular.

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4. FORSE et al. (US 5,821,217; issued on October 13, 1998) Enteral formulation: low in fat and containing protein hydrolysates (see entire document).

### ***Conclusion***

**NO claims are allowed.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SATYENDRA K. SINGH whose telephone number is (571)272-8790. The examiner can normally be reached on 9-5MF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Satyendra K. Singh/  
Examiner, Art Unit 1657

/Irene Marx/  
Primary Examiner  
Art Unit 1651